

REMARKS

Claims 1-4, 6-8 and 10 presently appear in this case. No claims have been allowed. The Official Action of March 31, 2005 has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention is directed to methods for treating conditions wherein TNF is to be eliminated from the body or its effect in the body is to be antagonized by administering the TNF-binding protein of the present invention.

Claims 1-4, 6-8 and 10 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Seckinger in view of Dayer for the reasons of record. Examiner states that Applicant's Declaration under 37 C.F.R. § 1.132 was insufficient to overcome the prior art rejection as the term "substantially purified" does not sufficiently define over the prior art. This rejection is respectfully traversed.

All of the present claims have now been amended to specify that the material being administered is the active ingredient of a pharmaceutically acceptable composition. In order to be pharmaceutically acceptable, there cannot be impurities in the protein preparation, such as extraneous proteins, that would prevent a composition from obtaining approval by appropriate regulatory authorities. Very

substantial purity is needed in order for a composition containing it to be pharmaceutically acceptable. Certainly the composition of Seckinger is not particularly pure and even if subjected to known purification procedures, there is no assurance that one could obtain the purity necessary to be pharmaceutically acceptable. The present specification teaches how to obtain the protein recombinantly so that it will therefore be free of any other human protein. This satisfies the claim requirement that the composition be pharmaceutically acceptable. Such would not have been obvious from any reading of Seckinger or Dayer.

The term "substantially purified" no longer appears in the claims and so there is no longer an issue as to how much purification is required by that term. It is now clear from the claim that the purification must be sufficient to allow any composition containing it to be pharmaceutically acceptable. This is supported, for example, by paragraph [0083] beginning on page 40 of the specification as well as paragraph [0084] and [0085].

Accordingly, the present claims define over any combination of the impure protein of Seckinger in view of Dayer. Reconsideration and withdrawal of this rejection is therefore respectfully urged.

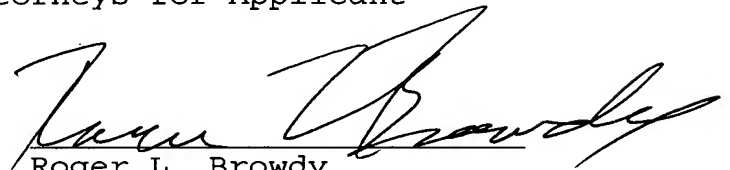
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Reply to Office Action of March 31, 2005

It is submitted that all the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. § 112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

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By

A handwritten signature in black ink, appearing to read "Roger L. Browdy", is written over a horizontal line.

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